JUDGE MOTZ

IN THE UNITED STATES DISTRICT COURT
SOUTHER DISTRICT OF NEW YORK

WILLIAM C. STONE, KATHLEEN BREMNER, AND CYNTHIA E. DIETZ, INDIVIDUALLY AND AS THE HEIRS OF PAULA PALLADINO, DECEASED
Plaintiffs,

v.

RANBAXY PHARMACEUTICALS, INC., AND RANBAXY LABORATORIES, LTD.,
Defendants.

10 CIV 8816

Case No. _____

PRODUCTS LIABILITY COMPLAINT AND JURY DEMAND

COMES NOW the Plaintiffs, WILLIAM C. STONE, KATHLEEN BREMNER, AND CYNTHIA E. DIETZ, INDIVIDUALLY AND AS THE HEIRS OF PAULA PALLADINO, by and through their undersigned attorney, **NAPOLI, BERN, RIPKA & ASSOCIATES,** and for their Complaint against Defendants, state and allege as follows:

1. This is an action to recover damages for personal injuries and the wrongful death of PAULA PALLADINO caused as the direct and proximate result of her use of the prescription drug ciprofloxacin. In support, the plaintiffs, allege the following:

I.

PARTIES

HEIRS AND PAULA PALLADINO, DECEASED

2. Plaintiff, William C. Stone, is a natural person, is a citizen and resides at 847 Marin Road, El Sobrante, Contra Costa County, California 94803.

3. Kathleen Bremner, is a natural person, is a citizen and resides at 14 Big Valley Road, Wurtsboro, NY 12790.

4. Cynthia Dietz, is a natural person, is a citizen and resides at 36 Big Valley Road, Wurtsboro, NY 12790.

5. Paula Palladino, a female of Italian descent, was a resident of 29 North Ferris Street, Irvington, Westchester County, New York 10533, and died on November 26, 2008, at ORMC-Horton Campus, in Middletown, Orange County, New York, from her exposure to defendant's drug, ciprofloxacin.

6. As more particularly pled below, plaintiffs maintain that Ciprofloxacin is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

DEFENDANTS

7. RANBAXY PHARMACEUTICALS, INC., is a pharmaceutical drug manufacturer and is a New York corporation, with its principal place of business located at 600 College Road East, Suite 2100, Princeton, New York, 08540, and can be served with service of process at its principal place of business.

8. RANBAXY LABORATORIES, LTD., is a pharmaceutical drug manufacturer and is the parent corporation of defendant, RANBAXY PHARMACEUTICALS, INC. RANBAXY LABORATORIES, LTD, is a foreign corporation with its principal place of business at 25 Nehru Place, New Delhi, India. RANBAXY. RANBAXY LABORATORIES, LTD., United States agent is Abha Rant, located at its subsidiary RANBAXY PHARMCEUTICALS, INC., 600 College Road East, Princeton, New York 08540.

9. The Defendant pharmaceutical drug manufacturers shall be referred to collectively as "Drug Company Defendants."

II.

JURISDICTION AND VENUE

10. Jurisdiction exists as against the defendants, pursuant to 28 U.S.C. Section 1332, in that the Plaintiff, was a citizen and resident of the State of New York at the time of her death. Plaintiff died in Middletown, Orange County, New York, and the defendants are foreign corporations; thus, complete diversity exists between the parties; the amount in controversy exceeds the sum of $75,000.00; venue is proper under 28 U.S.C. Section 1391(2) as plaintiff ingested the drug in this district and was subsequently injured in this district; thus, a substantial part of the events or omissions giving rise to plaintiff's claim occurred in this district.

III.

STATEMENT OF FACTS

11. This is an action for the wrongful death of Paula Palladino which arose as a direct and proximate result of the Defendants' negligence and wrongful conduct in connection with prescribing, design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of ciprofloxacin.

12. Defendant's generic drug Ciprofloxacin is a fluroquinolone antimicrobial drug and is marketed and distributed through Defendant's Abbreviated New Drug Application (ANDA).

13. On or about October 6, 2008, Paula Palladino was prescribed defendant's ciprofloxacin. Paula Palladino was again prescribed ciprofloxacin on October 29, 2008, for a urinary tract infection.

14. On or about October 30, 2008, Paula Palladino began to develop a fever and a rash and sought medical treatment at the Orange Regional Medical Center.

15. On or about November 18, 2008, Paula Palladino was diagnosed as having Stevens Johnson Syndrome, a severe cutaneous disorder caused by her ingestion of defendants' drug.

16. On or about November 26, 2008, Paula Palladino, died as a result of her exposure to defendants' drug.

17. Defendants market, manufacturer, sell, compound, and distribute ciprofloxacin bearing National Drug Code 63304-0709-01, which was dispensed and administered to Paula Palladino on October 6, 2008, and again on October 29, 2008.

18. At all material times, Ciprofloxacin was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Drug Company Defendants.

19. Ciprofloxacin was heavily marketed directly to hospitals and consumers by the Drug Company Defendants as safe and effective when it is not; and, for uses which exceeded the U.S. Food and Drug approved indications.

20. The truth is, that Drug Company Defendants always knew, or if they had paid attention to the findings of their own studies, should have known, that Ciprofloxacin was not safe nor more efficacious agents in the same therapeutic class. More importantly though, Defendants knew or should have known that when taking Ciprofloxacin, the risk

of suffering a severe cutaneous reactions, including but not limited to Stevens Johnson Syndrome (SJS) and/or Toxic Epidermal Necrolysis (TENS) far outweigh any potential benefit.

21. Still, Drug Company Defendants hid results of studies and made false statements in their advertising, labeling, informational leaflets, pamphlets and promotional materials for the purpose of increasing their profits from ciprofloxacin sales.

22. Drug Company Defendants repeatedly thwarted the law and their duty to tell the public the truth about Ciprofloxacin they were over-promoting for profit.

23. Defendants hid bad facts about Ciprofloxacin and fabricated more favorable information so they could sell large quantities of Ciprofloxacin and make giant corporate profits.

24. In addition to misinforming physicians, hospitals and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also misinformed physicians about the proper types of patients who should be given Ciprofloxacin, the duration of its proper usage, and the applications for which it is safe and FDA approved.

25. Defendants' lying to physicians and to the public about the safety and efficacy of ciprofloxacin for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal that not only is ciprofloxacin not worth its price—it is dangerous.

26. The label for ciprofloxacin drug products, known as the "Package Insert" was developed by the Drug Company Defendants and accompanied all ciprofloxacin

prescription drug products and/or samples and was published in the Physician's Desk Reference.

27. Drug labeling is to include *accurate* information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, efficacy, contraindications, warnings, precautions and side effects.

28. Drug Company Defendants failed to fully, truthfully and accurately communicate the safety and efficacy of ciprofloxacin drug products and intentionally and fraudulently mislead the medical community, physicians, Paula Palladino and her physicians about the risks associated with ciprofloxacin.

29. Drug Company Defendants fraudulently and aggressively promoted Ciprofloxacin drug products to physicians for use in patients, such as Paula Palladino, through medical journal advertisements, use of mass mailings, and direct communications, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures, leaflets and hand outs as these materials downplayed the significance of the adverse effects of Ciprofloxacin.

30. At all relevant times hereto, Drug Company Defendants did not investigate the accuracy of the Ciprofloxacin drug product labeling.

31. Drug Company Defendants were negligent in failing to report published articles and overwhelming scientific evidence of the true effects described above to the FDA, healthcare providers and patients, including Paula Palladino.

32. Drug Company Defendants were required to report literature, papers; and, to undertake action to reflect truthful and accurate information in its labeling and promotional materials and failed to do so.

33. Drug Company Defendants are under a duty to ensure that their Ciprofloxacin drug product labels are accurate.

34. Drug Company Defendants failed to ensure its Ciprofloxacin warnings to the medical community were accurate and adequate and breached this duty.

35. Drug Company Defendants have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Ciprofloxacin drug products, the medical community, Paula Palladino and her physicians, and other foreseeable users and failed to fulfill this duty.

36. Drug Company Defendants breached their duty to the medical community, Paula Palladino and her physicians, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Ciprofloxacin, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of their Ciprofloxacin drug products.

37. Drug Company Defendants breached their duty to the medical community, Paula Palladino and her physicians, and other foreseeable users similarly situated because Drug Company Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Ciprofloxacin drug products to said persons and other foreseeable users.

38. Drug Company Defendants breached their duty to the medical community, Paula Palladino, physicians, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report significant data

concerning the lack of efficacy and side effects associated with Ciprofloxacin.

39. Drug Company Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in Ciprofloxacin drug product labels and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Paula Palladino, Paula Palladino's physicians and other foreseeable users.

40. At all times material hereto, Drug Company Defendants were aware of the serious side effects described herein which were caused by Ciprofloxacin drug products and failed to fulfill the obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, Paula Palladino, and other foreseeable users about the safety and efficacy of Ciprofloxacin drug products.

41. At all times material hereto, Drug Company Defendants knew or should have known that physicians and Paula Palladino were unaware of or did not fully appreciate the seriousness of the risks associated with use of Ciprofloxacin drug products and the lack of benefit

42. At the time Drug Company Defendants made the above-described representations, Paula Palladino and her physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

43. Paula Palladino serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Drug Company Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Ciprofloxacin.

44. In doing the acts alleged in this Complaint, Drug Company Defendants acted with oppression, fraud, and malice and Paula Palladino's heirs are therefore entitled to punitive damages to deter Drug Company Defendants and others from engaging in similar conduct in the future.

45. As a proximate result of the fraud and deceit of Drug Company Defendants, Paula Palladino died.

46. Drug Company Defendants have an absolute duty to disclose the true facts regarding the safety of Ciprofloxacin drug products to the medical community, to physicians and their patients, which they negligently and/or intentionally failed to do.

47. Drug Company Defendants have a duty to ensure that they had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of Ciprofloxacin were accurate which it negligently and/or intentionally failed to do.

48. Plaintiff would not have suffered injuries but for the above misrepresentations or omissions of Drug Company Defendants.

49. Drug Company Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Paula Palladino's wrongful death.

50. A reasonably competent physician who prescribed Ciprofloxacin and a reasonably competent Plaintiff, as Paula Palladino, who consumed Ciprofloxacin would not realize its dangerous condition.

51. The reasonably foreseeable use of Ciprofloxacin drug products involved substantial dangers not readily recognizable by Paula Palladino's physicians, who acted as ordinary, reasonable and prudent physicians would, when prescribing Ciprofloxacin to

ordinary, reasonable and prudent patients, such as Paula Palladino.

52. Drug Company Defendants' actions were intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences and acted only out of self interest and personal gain and evidenced a specific intent to cause harm to Paula Palladino.

53. Paula Palladino's death came about as a foreseeable and proximate result of the Drug Company Defendants' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the effects of exposure and ingestion of Ciprofloxacin to the medical community, physicians, and hospitals.

IV.

COUNT 1

DEFECTIVE DESIGN - PRODUCTS LIABILITY

54. Plaintiffs reallege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

55. At all relevant times the Drug Company Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling Ciprofloxacin.

56. Ciprofloxacin is defective and unreasonably dangerous to consumers.

57. At all times mentioned in this Complaint Ciprofloxacin was defective and/or unreasonably dangerous to Paula Palladino and other foreseeable users at the time it left the control of the Defendants.

58. Ciprofloxacin is defective in its design or formulation in that when it left the hands of the Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.

59. The foreseeable risks associated with the design or formulation of Ciprofloxacin, include, but are not limited to, the fact that the design or formulation of Ciprofloxacin is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

60. At all times material to this action, Ciprofloxacin was expected to reach, and did reach consumers in the State of New York and throughout the United States, including Paula Palladino, without substantial change in the condition in which it was sold.

61. Defendants, developed, marketed and distributed Ciprofloxacin drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of Ciprofloxacin.

62. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that Ciprofloxacin created a high risk of bodily injury and serious harm.

63. The dangerous propensities of Ciprofloxacin drug products were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time said Defendants distributed, supplied, or sold Ciprofloxacin, and not known to ordinary physicians who would be expected to prescribe Ciprofloxacin for their patients.

64. Ciprofloxacin drug products, as distributed, were defective and unreasonably dangerous inasmuch as Ciprofloxacin were not accompanied by warnings and instructions that were appropriate and adequate to render Ciprofloxacin reasonably safe for their

ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of Ciprofloxacin.

65. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of Ciprofloxacin drug products with knowledge that consumers would be exposed to serious danger.

66. At all times material to this action, Ciprofloxacin was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was placed in the stream of commerce in ways that include, but are not limited to one or more of the particulars:

(a) At the time Ciprofloxacin left the control of the Defendants Ciprofloxacin was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because Ciprofloxacin breached an express warranty or failed to conform to other expressed factual representations upon which Paula Palladino physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Paula Palladino's heirs seek recovery herein.

(b) Ciprofloxacin drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time Ciprofloxacin left the possession of the Defendants, and that such risks clearly outweighed the utility of Ciprofloxacin therapy or its therapeutic benefits, and subjected Paula Palladino to the risk of suffering severe cutaneous side effects, including SJS, TENS and/or death.

(c) At the time Ciprofloxacin left the control of the Defendants Ciprofloxacin possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time Ciprofloxacin left the

possession of the Defendants. Specifically, although the Defendants were well aware that Ciprofloxacin products could potentially cause severe side effects including death.

(d) The Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of Ciprofloxacin taking into account the characteristics of the Ciprofloxacin, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases Ciprofloxacin, such as Paula Palladino.

(e) Ciprofloxacin manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risks of injury from Ciprofloxacin drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about the risks of suffering severe cutaneous side effects, including SJS or TENS associated with the use of Ciprofloxacin.

(f) When placed in the stream of commerce of commerce, Ciprofloxacin was defective in design and formulation, making the use of Ciprofloxacin more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other similar drugs on the market;

(g) Ciprofloxacin was insufficiently tested.

67. The Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Paula Palladino's heirs seek recovery.

68. The Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of Ciprofloxacin that caused the damages for which Paula Palladino's heirs seek recovery.

69. The reasonably foreseeable use of Ciprofloxacin involved substantial dangers not readily recognizable by the ordinary physician who prescribed Ciprofloxacin or

the patient, including Paula Palladino, who consumed Ciprofloxacin drug products.

70. The Defendants knew that Ciprofloxacin drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that Ciprofloxacin were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

71. Paula Palladino and her physicians did not know, nor had reason to know, at the time of the use of Defendants' Ciprofloxacin drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

72. The above defects caused serious injuries to Paula Palladino when Ciprofloxacin was used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

73. In addition, at the time that Ciprofloxacin left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of death to Paula Palladino without impairing the reasonably anticipated or intended function of Ciprofloxacin. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of death without substantially impairing Ciprofloxacin's utility.

74. As a direct and proximate result of the wrongful acts of the Defendants, Paula Palladino suffered severe and irreparable bodily injury and died.

75. For the above reasons, the Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs for their loss and which will deter the Defendants and others from like conduct.

COUNT 2

MANUFACTURING DEFECT

76. Plaintiffs reallege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

77. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Ciprofloxacin.

78. At all times material to this action, Ciprofloxacin was expected to reach, and did reach consumers in the State of New York and throughout the United States, including Paula Palladino without substantial change in the condition from which it was sold.

79. At all times material to this action, Ciprofloxacin was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following particulars posing a serious risk of injury and death.

a. When placed in the stream of commerce, Ciprofloxacin contained manufacturing defects that rendered the product unreasonably dangerous;

b. Ciprofloxacin's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. Ciprofloxacin was not made in accordance with the Defendants' product specifications or performance standards; and,

d. Ciprofloxacin's manufacturing defects existed before it left the control of the Defendants.

80. As a direct and proximate result of the wrongful acts of the Defendants, Paula Palladino suffered severe and irreparable bodily injury and died.

81. For the above reasons, the Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs for their loss and which will deter the Defendants and others from like conduct.

COUNT 3

FAILURE TO WARN – PRODUCTS LIABILITY

82. Plaintiffs reallege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

83. Ciprofloxacin was defective and unreasonably dangerous when it left the possession of the Drug Company Defendants in that it contained warnings insufficient to alert consumers, including Paula Palladino and/or her health care providers, of the dangerous risks and reactions associated with Ciprofloxacin, including but not limited to its propensity to cause severe cutaneous reactions including SJS and TENS and death, despite the Drug Company Defendants' knowledge of the increased risk of these injuries over similar safer drugs on the market.

84. Ciprofloxacin was defective due to inadequate post-marketing warnings or instruction because after Drug Company Defendants knew or should have known of the risk and danger of serious bodily harm and/or death from the use of Ciprofloxacin, Drug

Company Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and/or death.

85. Paula Palladino was prescribed and used Ciprofloxacin for its intended purpose.

86. Paula Palladino could not have known about the dangers and hazards presented by Ciprofloxacin.

87. The warnings that were given by the Drug Company Defendants were not accurate, clear, complete and/or were ambiguous.

88. The warnings that were given by the Drug Company Defendants failed to properly warn physicians of the increased risks of SJS and TENS and death as a result thereof.

89. Paula Palladino, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Drug Company Defendants. The Drug Company Defendants had a continuing duty to warn Paula Palladino of the dangers associated with Ciprofloxacin. Had Paula Palladino received adequate warnings regarding the risks of Ciprofloxacin, she would not have used Ciprofloxacin.

90. As a direct and proximate result of Ciprofloxacin's defective and inappropriate warnings, Paula Palladino would not have suffered an untimely death.

91. As a direct and proximate result of the wrongful acts of the Drug Company Defendants, Paula Palladino suffered severe and irreparable bodily injury and died.

92. For the above reasons, the Drug Company Defendants are strictly liable under New York product liability law without regard to proof of negligence or gross

negligence.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in an amount, which will compensate the Plaintiffs for their loss and which will deter the Defendants and others from like conduct.

COUNT 4

NEGLIGENCE
PRODUCT LIABILITY ACT

93. Plaintiffs reallege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

94. Manufacturer Defendants had a duty to exercise reasonable and prudent care in the design, research, manufacture, marketing, advertisement, testing, applying for FDA approval, supply, promotion, packaging, sale, and distribution of Ciprofloxacin, including the duty to take all reasonable steps necessary to manufacture and sell a product that was not unreasonably dangerous to consumers and users of the product.

95. Defendants were negligent in that they manufactured and produced a defective product known as Ciprofloxacin, knew and were aware of the defect inherent in the product, failed to act in a reasonably prudent manner in marketing the product, and failed to provide adequate warnings of the product's defects.

96. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of Ciprofloxacin in interstate commerce, in that Defendants knew and had reason to know that a consumer patient's use and ingestion of Ciprofloxacin created a significant risk of suffering severe cutaneous reactions, including but limited to

Stevens Johnson Syndrome (SJS) and/or Toxic Epidermal Necrolysis (TENS), and other severe personal injuries, which physical injuries and diseases are permanent in nature, including, but not limited to, physical pain and mental anguish, physical impairment and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic illness proximately caused by Ciprofloxacin, the continued risk of requiring additional medical and surgical procedures.

97. Defendants' negligence included, but was not limited to, the following acts and omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Ciprofloxacin without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Ciprofloxacin while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Ciprofloxacin;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Ciprofloxacin was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Ciprofloxacin was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, Stevens Johnson Syndrome